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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,154	05/01/2001	Peter Boekstegers	07883.0033	2668

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EXAMINER	
CHATTOPADHYAY, URMI	
ART UNIT	**PAPER NUMBER**
3738	7

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/845,154	Applicant(s) BOEKSTEGERS, PETER	
	Examiner Urmi Chattopadhyay	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-88* is/are pending in the application.

4a) Of the above claim(s) *3,8,26,34-42,59-61 and 66-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7,9-25,27-33,43-58 and 62-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 May 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, species A.2 and B.1, claims 1, 2, 4-7, 9-25, 27-33, 43-58 and 62-65, in Paper No. 5 is acknowledged. The traversal is on the ground(s) that at least claims 1, 2, 6, 7, 10-25, 30-33 and 43-45 are generic claims readable on all the species and subspecies of Group I. This is not found partly persuasive because only claims 1 and 46 are considered generic to all the species and subspecies of Group I. Claims 3, 8, 26, 34-42, 59-61 and 66-88 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group and species/subspecies, there being no allowable generic or linking claim.

Response to Amendment

2. The Preliminary Amendment filed 2/24/03 has been entered as paper no. 6. The changes made to claims 1, 6, 10, 30, 32, 43 and 45 have been approved by the examiner.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "positioning tool 20" mentioned on page 13, line 1 of the specification is not shown in Figure 2 or any of the other figures. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the first mechanism including a stop mechanism and delivering the first mechanism including engaging the stop mechanism with at least one inner wall of the coronary vessel (claims 13-14) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The word "invention" on line 1 is legal phraseology that needs to be removed.

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claims 13 and 14 require the first mechanism to include a stop mechanism and delivering the first mechanism includes engaging the stop mechanism with at least one inner

wall of the coronary vessel, and engaging the stop mechanism includes expanding the stop mechanism. These limitations are not supported by the specification.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 58 and 62-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 15 recites the limitation "the left ventricle" in line 2. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 58 recites the limitation "the guidewire" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1, 2, 4-7, 9, 16, 17-19, 23-25, 27-33, 46-50, 52, 53-55, 57, 58 and 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall et al. (USPN 6,261,304 B1 as cited in applicant's IDS).

Hall et al. discloses a method for providing direct blood flow between a heart chamber and a coronary vessel with all the elements of claims 1 and 46, but is silent to forming a passageway in the heart wall at a location defined by the guide device and expanding a stent within the passageway. See Figures 11A-11F and column 14, lines 6-36 for embodiment including placing guide device (208) through an anterior and posterior wall of the coronary vessel (CA) and through a heart wall (MYO) between the heart chamber (LV) and the coronary vessel (CA). Hall et al. also teaches another embodiment of a method for providing direct blood flow between a heart chamber and a coronary vessel including forming a passageway in the heart wall at a location defined by the guide device and expanding a stent within the passageway. See Figures 32-35 and column 22 lines 16-39. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the method shown in Figures 11A-11F by replacing the shunt (220) with the stent and method of forming a passageway for the stent, shown in Figures 32-35. Rather than delivering a shunt over the guidewire using a delivery catheter, a balloon catheter will be fed over the guidewire and expanded to create a passageway in the heart wall, and then a balloon catheter carrying a stent will be fed over the guidewire to deliver and expand the stent within the passageway (claims 2, 4-7, 9, 27-33, 46-50, 58, 62-65). The stent will be able to maintain open the created passageway for direct blood flow better than the shunt by withstanding the compressive forces of the heart wall, thereby reducing the likelihood of collapse. The stent would also be at an angle within the heart wall, which advantageously provides downstream flow of blood from out of the stent into the coronary vessel.

Claims 16 and 52, see column 14, lines 20-21 for guide device being a guidewire.

Claims 17, 23-25, 53 and 57, see Figures 11A-11D and column 14, lines 6-36 for inserting hollow needle and guide device at predetermined angle through vessel walls and heart wall. It would have been obvious to avoid intracardiac structures during insertion of the needle in order to prevent damage to heart during the procedure.

Claims 18, 19, 54 and 55, see Figure 11C-11D for inserting guidewire through the hollow needle until an end of the guidewire rests in the heart chamber.

12. Claims 10-14 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall et al. in view of Phelps et al. (USPN 6,290,728 as cited in applicant's IDS).

Hall et al. discloses a method for providing direct blood flow between a heart chamber and a coronary vessel with all the elements of claims 1 and 46, but is silent to the second mechanism including a stop mechanism at a substantial proximal end of the stent during stent delivery and the method further comprising advancing the stent within the passageway until the stop mechanism engages the posterior wall of the coronary vessel, as required by claims 10-12 and 43-45. Phelps et al. teaches implanting a stent within the heart wall to direct blood flow between a heart chamber and a coronary vessel, wherein a stent is advanced within the heart wall until a stop mechanism at a substantial proximal end of the stent engages the posterior wall of the coronary artery. See Figures 2-4 and column 6, lines 5-14 for the dumbbell shaped balloon (14) providing as the stop. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the balloon and stent of the second mechanism of Hall et al. to the dumbbell balloon (14) and stent (10) of Phelps et al. in order for the balloon to flare out the ends of the stent, which maintain the stent in its proper position in the heart wall and provide a

seal between the coronary vessel and the outer heart wall. The dumbbell balloon will also by nature of its shape, provide as a stop against the posterior wall of the coronary vessel, as shown in Figure 3. With respect to claims 13 and 14, it would have also been obvious to one of ordinary skill in the art to form the passageway using a balloon (first mechanism) having the same dumbbell shape so to create a passageway that will accommodate the flared stent. This dumbbell balloon will also by nature of its shape, provide as a stop against the posterior wall of the coronary vessel.

13. Claims 15, 20-22, 51 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall et al. in view of Vanney et al. (USPN 6,029,672 as cited in applicant's IDS).

Hall et al. discloses a method for providing direct blood flow between a heart chamber and a coronary vessel with all the elements of claims 1 and 46, but is silent to measuring the distance from the anterior wall of the coronary vessel to the left ventricle prior to placing the guide device and measuring the depth of insertion of the hollow needle by viewing markings thereon, as required by claims 15, 20-22, 51 and 56. Vanney et al. teaches measuring the thickness of the heart wall by observing external gradation marks on the guide needle in order to select an implant with a myocardial portion of sufficient length. See column 7, lines 42-56 and Figures 18-19. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Vanney et al. to have the hollow needle of Hall et al. include markings in order to obtain the dimensions required to calculate the thickness of the heart wall and coronary vessel and all other required distances to select the proper size stent and catheter balloon.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.

Urmi Chattopadhyay
Art Unit 3738

David J. Isabella
Primary Examiner

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May 5, 2003